

Remarks

Claims 50-66 were pending in this matter. By way of the amendment of this date, claims 50-53 and 61 have been amended and claims 54 and 55 have been canceled. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 50-53 and 56-66 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

Claims 54 and 55 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. While Applicants respectfully disagree with the rejection (for example, the specification teaches vectors and methods for making cells and non-human host mammals wherein the PG1 gene has been disrupted by homologous recombination (see pages 104-116)), these claims have been canceled in the interest of expediting prosecution in this matter. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 50-52, 56-58, and 61-63 have been rejected under 35 U.S.C. § 102(b) as anticipated by Gu *et al.* (1991). The Office Action argues that the reference anticipates the claimed invention in that it teaches a contiguous region with a 100% match with 38 contiguous nucleotides of SEQ ID NO: 179. Applicants respectfully submit that Gu *et al.* fail to anticipate the claimed invention in that the cited reference fails to teach a contiguous span of at least 40 consecutive nucleotides of SEQ ID NO: 179. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 50 and 59-66 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Weier *et al.* (1991). The Office Action argues that Weier *et al.* teach an isolated human chromosome 8 and that the chromosome of the reference must anticipate the claim invention. While the Office Action does not so state, it appears that this rejection is based upon the doctrine of inherency. Applicants respectfully traverse.

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic (*In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993)) and to establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in

the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). Finally, in relying upon the theory of inherency, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990).

As disclosed in the specification (see Summary of the Invention at page 6), the present invention relates to the identification of a gene associated with prostate cancer (PG1) and a multiplicity of biallelic markers that are found within the coding and non-coding regions of PG1 (e.g., within SEQ ID NO: 179). While the claimed sequence is derived from chromosome 8, Applicants respectfully submit that the subject invention cannot be anticipated by Weier *et al.* as there is no teaching that the chromosome of the reference has the exact same sequence over any stretch of the chromosome. Indeed, the reference is silent with respect to any sequence or subsequence of SEQ ID NO: 179. As the Patent Office is aware, the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, that such descriptive matter would be so recognized by persons of ordinary skill, and inherency may not be established by probabilities or possibilities. In the case of the rejection of record, it is respectfully submitted that one skilled in the art would not recognize that the missing descriptive matter (SEQ ID NO: 179) would be found in the cited prior art and no extrinsic evidence has been adduced that makes clear that the sequence of SEQ ID NO: 179 (or an exactly identical sequence of at least 500 consecutive nucleotides of SEQ ID NO: 179) is necessarily present. Again, the mere fact that the sequence may be found in the chromosome taught by Weier *et al.* is insufficient to support a finding of anticipation for anticipation under the doctrine of inherency may not be established by probabilities or possibilities. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

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Claims 53-55 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Gu *et al.* in view of Capecchi *et al.* Applicants respectfully submit that this rejection is moot with respect to claims 54-55 and that the combination of references fails to render claim 53 unpatentable. As noted *supra*, the reference fails to teach a contiguous span of 40 nucleotides of SEQ ID NO: 179 and Capecchi *et al.* fail to remedy this defect in the combination of references. Accordingly, it is respectfully submitted that the combination of references fails to render the claimed invention *prima facie* obvious and reconsideration and withdrawal of the rejection is respectfully requested.

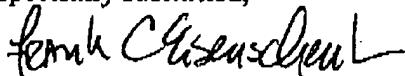
It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position. Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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